

REMARKS

Reconsideration of the application is respectfully requested in view of the following remarks:

1) Claim 41 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite with respect to use of the work “substantially”.

While it is submitted that one of ordinary skill in the art would know what was meant by “substantially transparent” and “substantially opaque”, in order to expedite prosecution, Applicant has deleted the term “substantially” (twice) in claim 41. Accordingly, withdrawal of the § 112 rejection of claim 41 is respectfully solicited.

2) Claims 34-36, 38, 39 41-43 and 45 are rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman et al. (U.S. 5,681,579) in view of Lorenz et al. (U.S. 5,258,421), evidenced by U.S. 4,832,009 and Applicant’s specification. Applicant respectfully traverses the rejection of these claims.

None of the cited references teaches or suggests, either alone or in combination, Applicant’s dual-purpose multilayered wound dressing having both a membrane layer, which comprises a silicone-containing compound, as a bottom outermost layer of a multilayered composite structure, in which the membrane layer has an outer surface forming the bottom outermost surface of the multilayered composite structure and in which the bottom outermost surface of the multilayered structure formed by the outer surface of the member layer forms a wound contacting surface having wound healing characteristics, and a foam layer as a top outermost layer of a multilayered composite structure, in which the foam layer has an outer surface forming the top outermost surface of the multilayered composite structure and in which

the top outermost surface of the multilayered composite structure formed by the outer surface of the foam layer forms a wound contacting surface having wound healing characteristics different from the wound healing characteristics of the outer surface of the membrane layer, as called for in the claims.

Neither Freeman et al. nor Lorenz et al. nor US Patent No. 4,832,009 discloses or suggests, either alone or in combination, a multilayered wound dressing comprising a multilayered composite structure having **both** a first wound contacting side formed by its bottom outermost layer having an outer surface that forms the bottom outermost surface of the multilayered composite structure with the bottom outermost surface forming a wound contacting surface having wound healing characteristics, and a second wound contacting side formed by its top outermost layer having an outer surface that forms the top outermost surface of the multilayered composite structure with the top outermost surface forming a wound contacting surface having wound healing characteristics different from the wound healing characteristics of the outer surface of the first wound contacting side of the multilayered wound dressing. There is no suggestion to be gleaned from these references to produce a multilayered wound dressing that has **both** a first wound contacting side having an outer surface that forms a bottom outermost surface of the multilayered composite structure with said bottom outermost surface forming a wound contacting surface having wound healing characteristics, and a second wound contacting side having an outer surface that forms a top outermost surface of the multilayered composite structure with said top outermost surface forming a wound contacting surface having wound healing characteristics different from a wound healing characteristics of the outer surface of the first side.

Freeman et al. disclose various wound dressings comprising a polymeric support layer

and an occlusive backing layer overlaying the support layer. Typically, an adhesive layer is applied to the outer face of the support layer, or to the inner surface of an overhanging portion of the occlusive backing layer, for adhering the dressing to the skin of a patient. Freeman et al. state at column 1, lines 8-13, that their invention is directed to new wound dressings that have a superior ability to absorb wound fluid and prevent dressing leakage and wound maceration.

Freeman et al. state that the dressings of their invention are particularly adapted for application on wounds that heavily exudate wound fluids during the healing process. Freeman et al.'s invention has an occlusive film layer 11 that is open to the atmosphere, and has an inner surface 13 which is the side toward the skin (please see column 4, line 15). Freeman et al. further state that their occlusive film layer 11 is selected from a material that is generally impervious to fluid transmission (please see column 4, lines 15-16). Also, Freeman et al. state at column 3, lines 57 to 61, that their invention provides a unique approach to wound care in that their invention provides for the rapid uptake of wound exudate away from the wound, while still providing a moist, occlusive, hydrocolloid environment for wound healing. Clearly, Freeman et al. do not disclose a dual-purpose wound dressing having two different wound contacting outer surfaces having two different wound healing characteristics, as defined in Applicant's claim 34, in which the bottom outermost surface of the multilayered composite structure formed by the outer surface of the membrane layer forms a first wound contacting outer surface and in which the top outermost surface of the multilayered composite structure formed by the outer surface of the foam layer forms a second wound contacting outer surface. Freeman et al. not only fail to disclose a wound dressing having two different wound contacting outer surfaces having two different wound healing characteristics, in which the bottom outermost surface of the multilayered composite structure formed by the outer surface of the membrane layer forms a first

wound contacting outer surface and in which the top outermost surface of the multilayered composite structure formed by the outer surface of the foam layer forms a second wound contacting outer surface, but Freeman et al. actually teach away from such a wound dressing.

Freeman et al.'s dressing only accomplishes its purpose of providing for the rapid uptake of wound exudate away from the wound while providing a moist, occlusive, hydrocolloid environment for wound healing when the Freeman et al. dressing is oriented with Freeman et al.'s polymeric support layer 12 being in direct contact to the wound and the occlusive layer 11 being oriented above the polymeric support layer 12 and open to the atmosphere. Orienting Freeman et al.'s dressing in the opposite orientation would result in no exudate being absorbed by the Freeman et al. dressing since the occlusive film layer 11 if positioned against the patient's wound would block exudate from being absorbed by the Freeman et al. dressing since the occlusive film layer 11 is selected from a material that is generally impervious to fluid transmission, and therefore failure of the Freeman et al. dressing to provide for rapid uptake of wound exudate away from the wound.

Lorenz et al. teach a tacky gel used as a wound dressing material. Lorenz et al. further teach that this gel may be applied to a substrate film, including a silicone-polytetrafluoroethylene interpenetrating polymer membrane or film. Lorenz et al. specifically teach that the gel is intended to adhere to skin (please see column 2, line 34). Lorenz et al. teach that substrate films may be used as a backing material (please see column 5, line 55). Lorenz et al. teach away from a dressing designed with two different wound-contacting surfaces, as is recited in Applicant's claim 34 in which the bottom outermost surface of the multilayered composite structure formed by the outer surface of the membrane layer forms a first wound contacting outer surface and in which the top outermost surface of the multilayered composite structure formed by the outer

surface of the foam layer forms a second wound contacting outer surface, as to provide disparate wound healing characteristics depending on which face of the dressing is placed in contact with the wound, since Lorenz et al. explicitly call for a wound-contact face and an outer backing material. A fair reading of Lorenz et al. provides an understanding that the gel serves as the contact surface which is to be applied to the skin (please see column 5, lines 33-40). Lorenz et al. discuss backings for the gel. However, it is only the applicant's present invention in which a teaching or disclosure may be gained of a suggestion to provide a multilayered wound dressing comprising a multilayered composite structure which has a first wound contacting side formed by its bottom outermost layer having an outer surface that forms the bottom outermost surface of the multilayered composite structure with the bottom outermost surface forming a wound contacting surface having wound healing characteristics, and a second wound contacting side formed by its top outermost layer having an outer surface that forms the top outermost surface of the multilayered composite structure with the top outermost surface forming a wound contacting surface having wound healing characteristics different from the healing characteristics of the outer surface of the first side. Lorenz et al. discuss substrates or backings to be used in conjunction with the gel, the gel being the contact surface.

Moreover, it is respectfully submitted that the Examiner's reference to the backing being useful as a burn blanket for serious burns in Lorenz et al. is misplaced. What Lorenz et al. actually disclose is that the wrap can serve the function of cooling the burned area through the heat sink effect of water in the hydrophilic gel (please see column 6, lines 28-34). It is clear from a reading of Lorenz et al. that Lorenz et al. are not disclosing a first surface and a second surface which may be placed in contact with the wound but rather Lorenz et al. throughout rely upon the single, gel surface contacting the skin or wound. The function of cooling the burned area is

understood to be accomplished by the water in the hydrophilic gel, when the gel is contacting the skin. It is untenable from a reading of Lorenz et al. to arrive at the conclusion which the Examiner creates in the Office Action. Unlike applicant's invention, Lorenz et al. do not disclose or suggest placing a surface other than the gel in contact with the wound. Contrary to the Examiner's position, Lorenz et al. would not be relied on by one of ordinary skill in the art to arrive at the applicant's present invention.

One of ordinary skill would not be led by any teaching to reverse what Lorenz et al. actually disclose and rely upon for their invention. It would be unfair to impose upon one of ordinary skill in the art the ability to destroy a reference for what it actually discloses in order to then claim that that reference somehow teaches or suggests the applicant's invention.

U.S. Patent No. 4,832,009 states at col. 2, lines 34-44, that the bandage according to the invention of U.S. Patent No. 4,832,009 includes a backing sheet 15 having a top face 17 and a bottom face 19 and is formed from a semi-interpenetrating polymer network material, a pressure sensitive adhesive layer 25 applied to the bottom face 19 and a section of gauze 20 which partially covers the bottom face 19 of the backing sheet 15. The bottom face 19 faces the application site as the bandage is applied to the application site, and the top face 17 faces away from the application site. Accordingly, U.S. Patent No. 4,832,009 teaches away from a wound dressing having two different wound surface contacting outer surfaces compositing its bottom outermost surface and its top outermost surface, wherein said two different wound surface contacting outer surfaces have two different wound healing characteristics.

Freeman et al., Lorenz et al., and US Patent No. 4,832,009 do not show Applicant's claimed dressings, and there is no suggestion in these references to use the dressings of the references as intended and also in an "up-side down" orientation, if desired, so as to provide a

choice of wound healing characteristics from one dressing to a wound.

Freeman et al. disclose a dressing that has only one wound surface contacting outer surface. In the embodiment disclosed in Freeman et al.'s Fig. 1, the interior occlusive overhang portion with adhesive thereon does not contact the wound, but rather contacts skin surrounding the wound. Lorenz et al. also has only one wound surface contacting outer surface, with only the gel layer of the dressing being applied to the patient's wound. In Lorenz, if the tacky gel layer is not applied to the entire substrate layer, the non-gel coated inner surface of the substrate layer may be provided with an additional adhesive which contacts the intact skin while the absorbent adhesive gel layer contacts the wound. Similarly, US Patent No. 4,832,009 has only one wound surface contacting outer surface. Accordingly, there is nothing in the references, either taken alone or in combination, that suggests a wound dressing having two different wound surface contacting outer surfaces having two different wound healing characteristics.

Claims 35, 36, 38, 39, 41-43, and 45 depend directly or indirectly from Applicant's claim 34 and are patentable for the same reasons claim 34 is patentable. Further, these claims add additional claim elements which further define Applicant's invention over the cited references.

Regarding the Examiner's statement that "Aesthetic design changes do not impart patentable significance with regard to the mechanism in which the wound article functions" with regard to claim 41, Applicant notes that claim 41 does not merely recite an aesthetic design change. Applicant's claim 41 calls for a pigmented adhesive layer that provides a visual indicator for differentiating one side of the dressing from the other side of the dressing in the field. None of the references discloses pigment mixed into an adhesive connecting a transparent layer to an opaque layer to distinguish one side of the dressing from the other side of the dressing. This is **structurally** completely different from dying a membrane layer. Applicant's wound dressing

permits the entire membrane layer to remain unaffected colorwise, but still have a color orienting indicator. It is respectfully submitted that the statement in the Office Action that "...it is considered prima facie obvious to add a pigment to any layer to distinguish it from other layers" is not supported with any authority. Moreover, the addition of pigment to Applicant's adhesive layer is not to distinguish Applicant's adhesive layer from other layers in Applicant's wound dressing. Rather, the addition of pigment into Applicant's adhesive layer permits one side of the wound dressing to be visually distinguished from the other out in the field (e.g., one side would appear as the color of the pigment and the other the color of the opaque foam layer).

Further, although actions taken in foreign patent offices are certainly not determinative in the prosecution of a counterpart U.S. patent application, they clearly indicate what other patent offices found on the merits in counterpart applications. Here, patents have issued in foreign counterpart applications corresponding to the above-captioned U.S. application, including European Patent No. EP 1267763, Chinese Patent No. 1269464, Canadian Patent No. 2,396,218, Israeli Patent No. 150,569, and Japanese Patent No. 2012055700, which is a secondary consideration supporting patentability in this pending U.S. application.

Based on the above, it is respectfully solicited that the §103(a) rejection of the claims be withdrawn.

3) Claim 44 is rejected under 35 U.S.C. §103(a) as being unpatentable over Freeman et al. (U.S. 5,681,579) in view of Lorenz et al. (U.S. 5,258,421), evidenced by U.S. 4,832,009 and Applicant's specification, as applied to claims 34-36, 38, 39, 41-43, and 45 above, and further in view of Nowakowski (U.S. 3,949,742). Applicant respectfully traverses the rejection of this claim.

As explained above, Applicant's claim 34 is patentable over Freeman et al. (U.S.

5,681,579) in view of Lorenz et al. (U.S. 5,258,421), evidenced by U.S. 4,832,009 and Applicant's specification, and the deficiencies of Freeman et al. (U.S. 5,681,579) in view of Lorenz et al. (U.S. 5,258,421), evidenced by U.S. 4,832,009 are not made up for by Nowakowski. Accordingly, Applicant's claim 44, which depends from Applicant's claim 34, also is patentable over the cited combination of references. The additional claim elements recited in claim 44 further distinguish Applicant's invention over the cited combination of references.

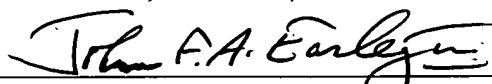
4) The independent claims of the withdrawn claims have been amended by adding to them the claim limitations set out in claim 34, which is now believed to be allowable.

Accordingly, rejoinder and allowance of the withdrawn claims are respectfully requested.

5) If necessary, an appropriate extension of time to respond is respectfully requested.

6) The Commissioner is authorized to charge any additional fees which may be required to Patent Office Deposit Account No. 05-0208.

Respectfully submitted,
HARDING, EARLEY, FOLLMER & FRAILEY, P.C.



John F. A. Earley III, Reg. No. 31,350
86 The Commons at Valley Forge East
1288 Valley Forge Road
P.O. Box 750
Valley Forge, PA 19482-0750
Telephone: 610-935-2300
Fax: 610-935-0600
Attorneys for Applicant

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